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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,880	10/22/2003	Nancy M. Lee	056367-2051	8369

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EXAMINER	
SCHLAPKOHL, WALTER	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/690,880	LEE ET AL.	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	wls

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-95* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-95* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-27, drawn to a panel of *polynucleotide* biomarkers as the claims read on **one combination** of polynucleotides selected from SEQ ID NOs: 1-22, classified in class 536, subclass 23.1.

II. Claims 28-48, drawn to a panel of *polypeptide* biomarkers as the claims read on **one combination** of polypeptides selected from SEQ ID NOs: 23-44, classified in class 530, subclass 350.

III. Claims 49-64, drawn to a method for measuring expression levels of *polynucleotide* biomarkers as the claims read on **one combination** of polynucleotides selected from SEQ ID NOs: 1-22 and as the claims read on **one combination** of primer sets selected from SEQ ID NOs: 45-50, classified in class 435, subclass 6.

IV. Claims 65-78, drawn to a method for measuring expression levels of *polypeptide* biomarkers as the claims read on **one combination** of polypeptides

selected from SEQ ID NOs: 23-44, classified in class 435, subclass 7.1.

V. Claims 79-88, drawn to kit comprising a reagent used in the analysis of *polynucleotide* expression levels of **one combination** of polynucleotides selected from SEQ ID NOs: 1-22 and wherein the reagent comprises **one combination** of primer sets selected from SEQ ID NOs: 45-50, classified in class 536, subclass 23.1.

VI. Claims 89-95, drawn to a kit comprising a reagent used in the analysis of *polypeptide* expression levels of **one combination** of polypeptides selected from SEQ ID NOs: 23-44, classified in class 530, subclass 350.

The inventions are distinct, each from the other, for the following reasons:

Groups I-VI are comprised of multiple independent and/or distinct inventions recited in the alternative which are the products or methods drawn to different polynucleotides/polypeptides which do not render obvious each other and thus are patentably distinct. Applicant must elect a single invention which is the product or method drawn to one

specific polynucleotide/polypeptide combination to which the claims will be restricted. Applicant must also indicate which claims are readable on the elected invention. This is not an election of species because the polynucleotides/polypeptides are different and distinct and thus the methods drawn to different and distinct polynucleotides/polypeptides are different and distinct inventions from each other.

Note: the non-standard format of this restriction, separating the inventions into multi-invention groups drawn to independent or distinct combinations of polynucleotides and polypeptides, followed by an election of a single invention drawn to one combination of polynucleotides or polypeptides within the elected multi-invention group, was done for the sake of compactness of the communication and clarity, instead of using the more standard format setting forth each separate invention drawn to each separate sequence which would require a much longer communication.

For related process inventions, the inventions are distinct if (a) the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; (b) the inventions as claimed are not obvious variants; and (c) the inventions as claimed are either not capable of use together or can have a materially different

design, mode of operation, function or effect. See MPEP § 802.01. The methods of Groups III and IV do not overlap in scope because the Group III invention comprises selecting a panel of polynucleotide biomarkers, isolating cellular RNA from a sample, amplifying copies of cDNA from the sample for each biomarker and quantifying the levels of cDNA amplified in the sample; whereas the Group IV invention comprises selecting a panel of polypeptide biomarkers, creating an antibody panel for each biomarker in the panel, using the antibody panel to bind the polypeptides of the sample, and quantifying the levels of polypeptides bound from the sample to the antibody panel. Furthermore, the Group III and IV inventions have a materially different design, mode of operation and/or effect since the respective biomarkers are chemically and structurally different. Moreover the Group III and IV inventions are not obvious variants because, for example, the creation of an antibody panel as in Group IV is not an obvious variation over amplification of copies of cDNA as in Group III.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions I and II are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions of Groups I and II do not overlap in scope because the Group I invention is comprised of a set of polynucleotide biomarkers and the Group II invention is comprised of a set of polypeptide biomarkers. The Group I and Group II inventions are not obvious variants due to their completely different structure and chemical properties. The Group I and Group II inventions also have a completely different design and mode of operation; for example, the Group I biomarkers are obtained by isolating nucleic acid from a biological sample and amplifying the nucleic acid whereas the

Group II panel biomarkers are obtained by isolating polypeptides from a biological sample with, e.g., the use of an antibody.

Similarly, Inventions V and VI are directed to related products. In the instant case, the inventions of Groups V and VI do not overlap in scope because the Group V invention is comprised of at least one reagent used in analysis of polynucleotide expression levels for a panel of biomarkers and the Group VI invention is comprised of at least one reagent used in the analysis of polypeptide expression levels for a panel of biomarkers of polypeptide biomarkers. The Group V and Group VI inventions are not obvious variants because the reagents for analysis of polypeptide expression and the reagents for analysis of polypeptide expression have different structures and chemical properties. The Group V and Group VI inventions also have a completely different design and mode of operation; for example, the Group V reagents comprise primer sets used in the preparation of cDNAs while the Group VI reagents comprise antibodies used for detection and quantitation of bound polypeptide.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions V & I and VI & II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combinations as claimed in Groups V and VI do not require the particulars of a particular subcombination as claimed, because the combinations (kits) are drawn to many different and distinct subcombinations of polynucleotide and/or polypeptide sequences which can be utilized in distinct and different biomarker panels for colorectal cancer and colorectal polyps. Furthermore, the claimed subcombinations have separate utility as biomarker panels for patient care including one or more of risk assessment, early diagnosis, establishing prognosis, monitoring patient treatment and detecting relapse.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status

in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions III and I & V and Inventions IV and II & VI are related as processes and products for their practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the processes as claimed can be practiced by utilizing any combination of polypeptides or polynucleotides in conjunction with any of the reagents for analysis of expression of the claimed products. For example, the Group III invention could be practiced with SEQ ID NOs: 1 and 2 and a reagent for amplification of those two SEQ ID NOs or Group III could be practiced with SEQ ID NOs: 3 and 4 and a reagent for amplification of the same SEQ ID NOs: 3 and 4.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in

the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Except for the specific relationships above, the inventions of Groups I and IV & VI, Groups II and III & V, Groups III and II & VI, Groups IV and I & V, Groups V and II & IV, and Groups VI and I & III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 808.01). In the instant case the methods of Groups III and IV have different modes of operation and are not disclosed as capable of use together with the inventions of Groups II & VI and Groups I & V, respectively. Similarly, the products of Groups I, II, VI and VI have different modes of operation are not disclosed as capable of use together with the inventions of IV & VI, III & V, II & IV and I & III, respectively.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in

the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during

prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily

from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

April 18, 2006

NANCY VOGEL
PRIMARY EXAMINER